K123431

JUN 17 2013

**510(k) SUMMARY**
(As required by 21 CFR 807)

| | |
|---|---|
| **TRADE NAME** | Dream Color |
| **CLASSIFICATION** | Class II (21 CFR 807.92) |
| **DATE SUBMITTED** | November 4, 2012 |
| **SUBMITTED BY** | DreamCon Co., Ltd.<br>469-1 Sanmak-dong, Yangson-si<br>Gyeongsangnam-do<br>Korea |
| **CONTACT** | Albert Rego, Ph.D.<br>Telephone Number: 949-770-8710 |
| **PREDICATE DEVICE** | K051477<br>Migwang<br>Comfort 38<br>Decision Date:03-10-2006 |

**DEVICE DESCRIPTION**

Dream soft contact lenses are hemispherical shape with molded spherical base curves and lathe-cut front surfaces. Its' sectional configuration has symmetrical shape. Back-cover surface except optic zone and edge side is colored with various colors.

The lenses are made of hydrophilic polymer of 2-Hydroxyethyl methacrylate(HEMA) and cross-linked with ethylene glycol dimethacrylate(EGDMA), plus an initiator. The copolymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. Lenses are tinted with one or a combination of one or more of the following 'listed' color additives: Titanium Dioxide, Iron Oxides, C.I. Pigment Green 7, (Phthalocyaninato(2-)) Copper and Reactive Black 5. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only amount of color additive need to accomplish the intended coloring effect.

In hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming colored optical surface. The hydrophilic properties of the lens require that it is maintained in a fully hydrated state in a solution compatible with the eye. If the lens dry out, it will become hard and appear somewhat warped. However, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

| | |
|---|---|
| **Refractive Index** | 1.428 (hydrated) |
| **Light Transmission** | greater than 90% |
| **Water Content** | 38 % + 2% |
| **Oxygen Permeability** | $9.77 * 10^{-11}$ ($cm^2$/sec)(ml $O_2$/ml * mm Hg 35°C), (revised Fatt method) |

**INDICATIONS FOR USE** The Dream Color I, II, and III (polymacon) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 0.50 diopters that does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eyes.
Eyecare practitioners may prescribe the above lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear the lens may be disinfected using a chemical disinfecting system

**TESTING** (All results met current Biocompatibility requirements per ISO 10993-1 consensus standards)

BAR-01 Biocompatibility Assessment Report
Cytotoxicity - Dream Color I & II
Sensitization - Dream Color I & II
Irritation - Dream Color I & II

VRC-02 Validation Report of Cleaning Process for Soft Contact Lens

BS-2009-KoTIMeD-010001 Dream Color I
Maximization test for Delayed hypersensitivity

MD 2007-035 Dream Color I, Dream Color II -
Shape and Appearance
Torsion Test
Diameter
Curvature Radius
Apex Flexibility
Extractable Substances
Cell Growth Inhibition test
Agarose Overlay Test
Ocular Irritation Test
Sterility Test - Direct Innoculation

MD 2008-033 Dream Color I - Gold, Gray
Water content
Extractables

MD 2011-033 Extractables

BS-2009-KoTIMeD-010002 Dream Color II - (Aqua, Blue)
Maximization test for Delayed hypersensitivity

MD 2007-036 Dream Color II - (Aqua, Blue)
Shape and Appearance
Torsion Test
Diameter
Curvature Radius
Apex Flexibility
Extractable Substances
Cell Growth Inhibition test
Agarose Overlay Test
Ocular Irritation Test
Sterility Test - Direct Innoculation

MD 2008-034 Dream Color II - (Aqua, Blue)
Water content
Extractables

VRS-01 Validation Report: Sterilization

VRP-02 Validation Report: Packaging Process

MD 2007-037 Dream Color II - Physicochemical Test Report

TRC-01 30 Cycle Cleaning Validation

**SUMMARY OF SUBSTANTIAL EQUIVALENCE**
**Comparison to Predicate Device(s):**

This device is substantially equivalent to the predicate devices in its intended use and technological characteristics, manufacturing process specified in following table;

| Substantial Equivalency | Soft (hydrophilic) contact lens | |
|---|---|---|
| Manufacture | MiGwang Contact Lens Co., Ltd. | Dreamcon Co., Ltd. |
| Article name | Migwang Comfort 38 | Dream Color |
| Material<br>USAN name | Polymacon | Polymacon |
| Type | Spherical, Toric | Spherical |
| FDA Classification | Lenses, Soft Contact, Daily Wear (Class II) | Lenses, Soft Contact, Daily Wear (Class II) |
| Water Content | 38±2% | 38±2% |
| Light Transmittance | >90% | >90% |

| | | |
|---|---|---|
| Index of Refraction | 1.43 | 1.428 |
| Oxygen permeability | $9.77 * 10^{-11}$ ($cm^2$/sec)(ml $O_2$/ml * mm Hg @ 35°C) | $9.77 * 10^{-11}$ ($cm^2$/sec)(ml $O_2$/ml * mm Hg @ 35°C) |
| Manufacturing Method | Lathe-cut (semi molded) | Lathe-cut (semi molded) |
| Sterilization | Steam Validated Autoclave | Steam Validated Autoclave |
| Packaging | Blister Pack & vial | Blister Pack & vial |
| Visibility tint | Titanium Dioxide; 21CFR 73.3126 | Titanium Dioxide(White); 21CFR 73.3126 |
| Visibility tint | Iron Oxides; 21CFR 73.3125 | Iron Oxides(Red); 21CFR 73.3125 |
| Visibility tint | C.I Pigment Green 7; 21CFR 73.3124 | C.I Pigment Green 7; 21CFR 73.3124 |
| Visibility tint | (Phthalocyaninato(2-)) Copper; 21CFR 74.3045 | (Phthalocyaninato(2-)) Copper; 21CFR 74.3045 |
| Visibility tint | C.I. Reactive Black 5 21CFR 73.3121 | Reactive Black 5 21CFR 73.3121 |
| Tint Process | Entrapment | Entrapment |
| Indication | Soft Contact Lenses for daily wear are indicated for the correction of visual in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopter, and/or are presbyopia. NOTE: Refractive astigmatism and presbyopia N/A for spherical lenses. | Soft Contact Lens for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia). |
| Powers | +25.00 ~ -25.00 Diopter | +25.00 ~ -25.00 Diopter |
| Total diameter | 12.8 ~ 14.8 | 13.5 ~ 14.5 |
| Geometrical center thickness | 0.03 ~ 0.30 | 0.03 ~ 0.50 |
| Curvature | 8.0 ~ 9.5 | 8.3 ~ 9.0 |
| Optic zone | 6.0 ~ 12.5 | 6.0 ~ 12.5 |
| Radial edge thickness | 0.03 ~ 0.12 | 0.03 ~ 0.05 |
| Color | brown, gray, aqua, blue, violet, green | brown, gray, aqua, blue |
| Toxicity(Safety) | Non-Toxic | Non-Toxic |
| Tensile Strength (MPa) | 0.427 | 0.425 |
| % Elongation to Break | 128% | 127% |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

Dreamcon Co. Ltd.
% Albert Rego, Ph.D.
27001 La Paz Road, Ste. 312
Mission Viejo, CA 92691

Re: K123431
Trade Name: Dream Color I, II, and III (polymacon) Soft (hydrophilic) Contact Lenses
Regulatory Class: II
Product Code: LPL
Dated: June 1, 2013
Received: June 11, 2013

Dear Dr. Rego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):____K123431

Device Name:__Dream Color I, II, and III (polymacon) Soft (hydrophilic) Contact Lenses

Indications for Use:

The Dream Color I, II, and III (polymacon) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 0.50 diopters that does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eyes. Eyecare practitioners may prescribe the above lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear the lens may be disinfected using a chemical disinfecting system

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph C. Hutter -S
2013.06.17 08:17:41 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number__K123431_____